

REMARKS

STATUS OF THE CLAIMS

Claims 19 and 25-43 were pending and under examination. By amendment herein, claim 32, 36 and 37 have been amended as shown above. Claim 40 has been canceled, without prejudice or disclaimer. Thus, claims 19, 25-39 and 41-43 are pending.

INFORMATION DISCLOSURE STATEMENT

Applicants note with appreciation receipt of the signed and initialed 1449 forms.

DRAWINGS

Applicants note with appreciation that the drawings have been approved by the draftsperson.

35 U.S.C. § 132

The Examiner continues to object to Figure 3 and the revised Sequence Listing containing SEQ ID NO:5, alleging that the sequence depicted in this Figure was not a part of the specification as originally filed. (Final Office Action, page 3). In support of this objection, the Examiner maintains that (1) the fact that a sequence is publicly available at the time of filing is irrelevant and (2) correcting errors in sequence listings is improper.

Applicants traverse the rejection and both supporting remarks.

As set forth in M.P.E.P. § 2163.07, amendments to the specification do not constitute new matter if they correct an obvious error, where one skilled in the art would recognize the existence of error and the appropriate correction. M.P.E.P. § 2163.07, citing *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). Furthermore, the legal determination that sequences can be added or changed without introducing new matter is also sanctioned in instances in which the issue is whether the claims are adequately described by the specification. *See, e.g.*, M.P.E.P. § 2163 citing *In re Oda* and stating that with "respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. *See, e.g.*, Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998). *e.g.*, Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998). In other words, it is well settled that the public availability of a correct amino acid sequence at the time of filing is entirely relevant to the question of whether submission of a known sequence constitutes the addition of new matter.

In the pending case, the submission of Figure 3 does not constitute new matter. Instead, Figure 3 provides a wild type LT-A sequence that corrects obvious errors in many published sequences. Thus, as previously noted, the pre-filing date existence of a GenBank entry corresponding to FIG. 3 clearly establishes that Applicants are correcting an obvious error that would have been recognized as such by the skilled artisan.

Thus, there is nothing in the previous amendments that goes beyond the originally filed subject matter and, accordingly, new matter has not been added. Therefore, Applicants request that this objection be withdrawn.

35 U.S.C. § 112, NEW MATTER

The Examiner alleged that claims 37-43 contain new matter not described in the specification as originally filed and, accordingly, has invited Applicants to point to specific line and page numbers that provide support of these claims.

Pursuant the Examiner's invitation, Applicants note that support of the limitations of pending claims 37-39 and 41-43 can be found as follows:

Recitation	Support
bacterial antigen	page 19, line 15: "bacterial antigens such as those derived from ..."
<i>Bordetella pertussis</i> antigens	page 19, line 19: " <i>Bordatella pertussis</i> "
<i>Helicobacter pylori</i> antigens	page 19, line 21: " <i>Helicobacter pylori</i> "
meningococcus A antigens	page 19, lines 19-20: " <i>Neisseria meningitides</i> (A, B, C, Y)"
meningococcus B antigens	page 19, lines 19-20: " <i>Neisseria meningitides</i> (A, B, C, Y)"
meningococcus C antigens	page 19, lines 19-20: " <i>Neisseria meningitides</i> (A, B, C, Y)"

Thus, pending claims 37-39 and 41-43 all find support in the specification as filed. Accordingly, withdrawal of this objection is respectfully requested.

35 U.S.C. § 112, SECOND PARAGRAPH

Claims 32-43 were rejected as allegedly indefinite. (Final Office Action, page 4). In particular, claims 37 and 41-43 were alleged to be vague and confusing in the recitation "meningococcus A antigens" because "it is unclear whether or not the letters A, B, and C refer to antigen of meningococcus, strain designations or serogroups." (Final Office Action, page 5). 19 stands rejected as allegedly confusing in its double recitation of the term "toxin." (Office Action,

page 5). In addition, claims 32 and 35 (and claims dependent therefrom) were alleged to be vague for the use of abbreviations. *Id.* Applicants address each rejection in turn.

A. Claims 32-43

The definiteness requirement of 35 U.S.C. § 112, second paragraph is satisfied if it is clear to the skilled artisan what is meant by a particular claim term. *See, e.g., In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). Further, the definiteness and clarity of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular disclosure; (2) the teachings of the art; and (3) the claim interpretation that would be given by one possessing ordinary skill in the pertinent art at the time the invention was made. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 202 (Fed. Cir. 1983). In other words, the terms at issue must be read in context of the application and field of endeavor.

Applicants submit that the terms "meningococcal A/B/C antigens" clearly refer to antigens derived from particular serogroups of *Neisseria meningitides*. The term is clearly used in a conventional sense that would be readily understood by the skilled artisan. *See, e.g.,* Dorland's Illustrated Medical Dictionary, 28th edition stating that *N. meningitidis* is "differentiated serologically into four main groups (A, B, C, D) and several provisional groups..." copy attached hereto.

Thus, when properly read in light of the state of the art and the specification as filed, claims reasonably apprise those skilled in the art as to the metes and bounds of the claimed subject matter and is more than sufficiently precise. Accordingly, withdrawal of this rejection is respectfully requested.

B. Claims 32 and 35

In view of the foregoing amendments spelling out the abbreviations in claims 32 and 35, Applicant submit that the rejections have been obviated. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and the Office's acknowledgment that the amended claims define an invention that is free of the prior art as well as described and enabled by the specification, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further communications regarding this application to:

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Seldinger n., a needle with a blunt, tapered external cannula with a sharp obturator; used for the initial percutaneous insertion characteristic of the Seldinger technique for arterial or venous access.
Silverman n., an instrument for taking tissue specimens, consisting of an outer cannula, an obturator, and an inner split needle with longitudinal grooves in which the tissue is retained when the needle and cannula are withdrawn.
skinny n., fine n.
stop n., a needle with a shoulder that prevents it from being inserted beyond a certain distance.
swaged n., one permanently attached to the suture material.
transseptal n., a needle used to puncture the interatrial septum in transseptal catheterization.
Vim-Silverman n., a needle used in needle biopsy.

NEFA nonesterified fatty acids.

ne-flu-o-ro-pho-tom-e-ter (nə-fluor'ō-fō-tom'ē-tər) fluoronephelometer.

nef-o-pam hy-dro-chlo-ride (nəf'ō-pam) chemical name: 3,4,5,6-tetrahydro-5-methyl-1-phenyl-1H-2,5-benzoxazocine hydrochloride; an analgesic and muscle relaxant, C₁₇H₁₉NO·HCl.

Neg-a-tan (neg'ā-tan) trademark for a preparation of negatol.

neg-a-tiv-ism (neg'ā-tiv-iz'm) resistance or opposition to advice, suggestions, or commands; e.g., in catatonic schizophrenia the patient may lower his arms if asked to raise them or may resist efforts to move them.

neg-a-tol (neg'ā-tol) a colloidal product obtained by reacting metacresol sulfonic acid with formaldehyde; used as a parasiticide, germicide, and bacteriostatic, for topical application to the cervix.

neg-a-tron (neg'ā-tron) the negative electron; see *positron* and *electron*.

Neg-Gram (neg'ram) trademark for preparations of nalidixic acid.

neg-lect (nə-glekt') [L. *neglegere* to disregard] disregard of or failure to perform some task or function.

unilateral n., hemiparaxia with failure to pay attention to bodily grooming and stimuli on one side but not on the other, usually due to a lesion in the central nervous system, as after a stroke. Called also *selective inattention*. Cf. *dressing apraxia*.

Negri bodies (nə'gre) [Adelchi Negri, Italian physician, 1876–1912] see under *body*.

Negri-Ja-cod syndrome (nə'gre-zhah-kō') [Silvio Negri, Italian physician, 20th century; Maurice Jacod, French physician, 20th century] Jacod's syndrome.

Negro's phenomenon (sign) (nə'grōz) [Camillo Negro, Italian neurologist, 1861–1927] see *cogwheel rigidity*, under *rigidity*.

Ne-her (nə'her) Erwin. German biophysicist, born 1944. Co-winner with Bert Sakmann of the Nobel prize for medicine or physiology in 1991 for their work on cellular communications involving electrical signals, particularly their study of ion channels.

NEI National Eye Institute.

neigh-ber-wise (nə'bor-wīz) descriptive of the plastic behavior of transplanted embryonic cells or tissue in a manner appropriate to its new and strange location. Cf. *selfwise*.

Neil-Moo-ser bodies, reaction (nēl-mō'zer) [Mather Humphrey Neill, American physician, 1882–1930; Hermann Mooser, Swiss pathologist, 1891–1971] see under *body* and *reaction*.

Neisser's diplococcus (nī'serz) [Albert Ludwig Siegmund Neisser, German physician, 1855–1916] see *Neisseria gonorrhoeae*.

Neisser-Wechs-berg phenomenon (nī'ser-veks'berg) [Max Neisser, German physician, 1869–1938; Friedrich Wechsberg, German physician, 1873–1929] see *complement deviation*, under *deviation*.

Neisseria (nī-se're-ā) [A.L.S. Neisser] a genus of bacteria of the family Neisseriaceae, consisting of gram-negative, oxidase-positive cocci characteristically coffee bean-shaped and paired. The organisms are aerobic or facultatively anaerobic and are part of the normal flora of the oropharynx, nasopharynx, and genitourinary tract. The genus includes the gonococcus, the several meningococci types, pigmented forms occasionally associated with meningitis, and a number of saprophytic or parasitic but nonpathogenic species.

catarrha'lis, Moraxella (Branhamella) catarrhalis.

flaves'cens, a species characterized by the production of yellow pigmented colonies. It is sometimes found in the body fluids of patients with meningitis and septicemia.

gonorrhoe'ae, the specific etiologic agent of gonorrhea, occurring typically as pairs of flattened cells, found primarily in purulent urethral discharges. Called also *diplococcus* of Neisser.

lacta'mica, a species that ferments lactose, found frequently in

throat and nasopharyngeal cultures of infants and young children; it occasionally causes endocarditis and meningitis in humans.

N. meningi'tidis, a prominent cause of meningitis and the specific etiologic agent of meningococcal meningitis. The species is differentiated serologically into four main groups (A, B, C, D) and several provisional groups; group C is the most important pathogen. Called also *meningococcus*.

N. muco'sa, a species that produces mucoid colonies that are often adherent; it is found in the human nasopharynx and is occasionally pathogenic, causing pneumonia. Called also *Diplococcus mucosus*.

N. sic'ca, a species characterized by dry grayish or slimy white or yellow colonies, which is part of the normal flora of the human nasopharynx, saliva, and sputum.

N. subfla'va, a species that produces smooth, yellow-pigmented colonies, found in the human nasopharynx and occasionally in cerebrospinal fluid in cases of meningitis.

Neis-se-ri-a-ceae (nī-se're-ā-se-ē) a family of gram-negative, aerobic cocci and rod-shaped bacteria occurring singly or in pairs, short chains, or masses. The organisms are parasitic or saprophytic, and some produce pigment. The family includes four genera: *Acinetobacter*, *Kingella*, *Moraxella*, and *Neisseria*.

neis-se-ri-al (nī-se're-āl) of, relating to, or caused by *Neisseria*.

nekr(o)- for words beginning thus, see those beginning *necr(o)-*.

nek-ton (nek'ton) [Gr. *nēktos* swimming] collective term for marine organisms that swim actively, as contrasted with plankton.

Né-la-ton's catheter, line, sphincter, syndrome (nə-lah-tawz') [Auguste Nélaton, French surgeon, 1807–1873] see under *catheter*, *line*, and *sphincter*, and see *hereditary sensory radicular neuropathy*, under *neuropathy*.

Nel-son's syndrome (nel'sənz) [Don H. Nelson, American internist, born 1925] see under *syndrome*.

ne-ma (nə'mə) [Gr. *nēma* thread] a nematode.

nem-a-line (nem'ā-lēn) [Gr. *nēma* thread] threadlike or rod-shaped.

nem-a-thel-minth (nem'ā-thel'minth) [*nemato-* + Gr. *helmins* worms] a worm of the phylum Nematelminthes.

Nēm-a-thel-min-thes (nem'ā-thəl-min'thēz) in some systems of classification, a phylum including the Acanthocephala and Nematoda.

nem-a-thel-min-thi-a-sis (nem'ā-thel'min-thi'ā-sis) infection by nematodes, or roundworms.

ne-mat-i-cide (nə-mat'ī-sīd) nematocide.

nem-a-ti-za-tion (nem'ā-tī-zā-shən) infection with nematodes, or roundworms.

nemat(o)- [Gr. *nēma* thread, gen. *nēmatos*] a combining form denoting relationship to a nematode, or to a threadlike structure.

nem-a-to-blast (nem'ā-to-blast) [Gr. *nēma* thread + *blastos* germ] spermatid.

Nem-a-toc-era (nem'ā-tos'ər-ə) [Gr. *nēma* thread + *keras* horn] a suborder of Diptera characterized by having antennae of many segments and comprising the gnats, mosquitoes, midges, black flies, craneflies, gallflies, etc.

nem-a-to-cide (nem'ā-to-sīd) [*nemato-* + L. *caedere* to kill] 1. destructive to nematode worms. 2. an agent that destroys nematodes.

nem-a-to-cyst (nem'ā-to-sist') a minute stinging structure, found in the cnidoblasts of jellyfish and other coelenterates, used for anchorage, for defense, and for the capture of prey.

Nem-a-to-da (nem'ā-to'dā) [Gr. *nēma* thread + *eidos* form] a class of tapered cylindrical helminths, the roundworms, of the phylum Aschelminthes, many species of which are parasites. They are characterized by longitudinally oriented muscles and by a triradiate esophagus. In some systems of classification, they are considered to be a separate phylum. Sometimes called *Nemathelminthes*, or a class under that phylum.

nem-a-tode (nem'ā-tōd) a roundworm; any individual belonging to the class Nematoda.

nem-a-to-des-ma (nem'ā-to-dez'mā) pl. *nematodesma'ta* [*nemato-* + Gr. *desmos* band, ligament] a bundle of parallel microtubules serving to support the cytostome and cytopharyngeal apparatus and associated organelles of certain ciliate protozoa; also seen in certain flagellate groups. Called also *trichite*.

n-m-a-to-di-a-sis (nem'ā-to-dī'ā-sis) infection by a nematode parasite.

Nem-a-t-di-rus (nem'ā-to-dī-rəs) a genus of nematode parasites belonging to the family Trichostrongylidae, found in the duodenum of ruminants.